

Application No. 10/634370
Page 6

Amendment After Final
Attorney Docket No. S63.2N-7132-US03

Remarks

This Amendment is in response to the Office Action dated **September 21, 2005**. Claims 33-48 are pending in this application. Claims 38 and 42-48 have been withdrawn from consideration. The Office Action objects to the specification; rejects claim 33 citing 35 USC § 112, first paragraph; and rejects claims 33-37 and 39-41 citing 35 USC § 103 over Wang et al. (US 5807520; hereinafter "Wang") in view of Wand et al. (US 5525388; hereinafter "Wand").

By this Amendment, the specification is amended to correct typographical errors. Reconsideration in view of the following remarks is requested.

Specification

The Office Action objects to the specification, alleging that the Amendment filed on January 25, 2005 introduces new matter. More specifically, it was asserted that the original specification does not disclose a mandrel 200 being disposed inside tubing segment 120. This objection is traversed.

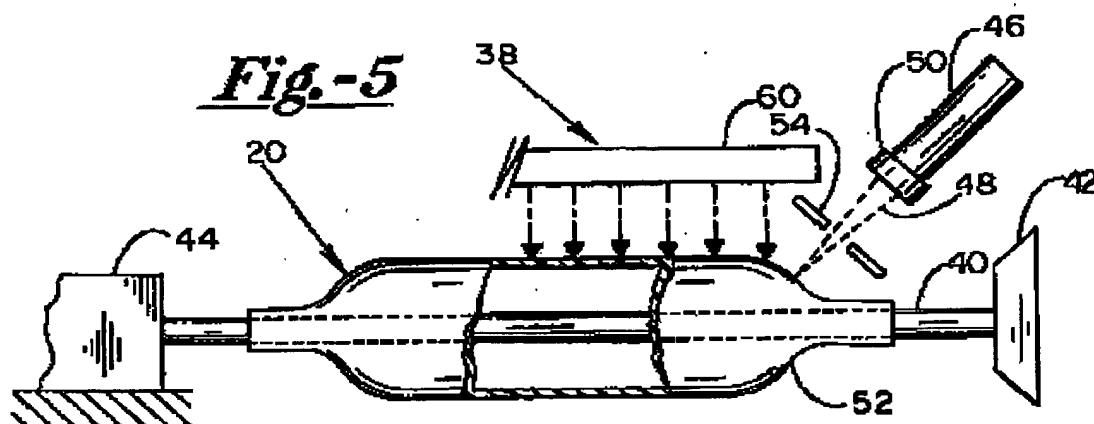
In the Response After Final filed June 20, 2005, Applicants argued that a person of ordinary skill in the art would recognize that in order for the mandrel to support the segment in the manner described, the mandrel must be positioned within the segment 120. In support of the argument, Applicants submitted the Declaration in support of patentability under § 1.132 of David Parsons. It appears that the Declaration may not have been considered because the outstanding Final Office Action did not comment on the Declaration. Applicants hereby reassert the arguments previously filed and request that the Declaration be considered.

Further, Applicants assert that Forman (US 5826588), incorporated by reference into the immediate Application (see page 3, last paragraph), clearly discloses a mandrel 40 being disposed inside a balloon. Figure 5 of Forman is provided below for convenience. Forman further discloses that the mandrel 40 is rotatable about a longitudinal axis, and that the balloon rotates with the mandrel 40. See column 7, lines 1; 5-6; and 21.

"The information incorporated [by reference] is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed." MPEP 2163.07(b).

Application No. 10/634370
Page 7

Amendment After Final
Attorney Docket No. S63.2N-7132-US03



Keith (US 5087394) discloses an internal support mandrel 32 that is oriented within a balloon. See Figures 2 and 3; and column 5, line 22. Keith was also incorporated by reference into the immediate Application (see page 2, line 19 and page 4, lines 16-18).

Therefore, Applicants assert that the concept of a mandrel disposed inside a balloon or tubing segment was contained in the application as filed, and request withdrawal of the objection to the specification.

In light of the above remarks, if the Examiner still objects to the specification as containing new matter, Applicants request that the Examiner explain why the Declaration of David Parsons is not persuasive.

Also, by this Amendment, the specification is amended to correct typographical errors. In the paragraph beginning at page 2, line 18, two occurrences of "4,963,37" are corrected to read "4,963,313." These amendments are supported by Application No. 09/076,252, now US 6024752, to which the immediate Application claims priority. In the paragraph beginning at page 4, line 12, an occurrence of "4,47,989" is corrected to read "4,413,989." Support for this amendment is inherent in that "4,47,989" is not a patent issued to Schjeldahl et al., while US 4,413,989 is a patent issued to Schjeldahl et al. that illustrates materials and methods of making catheter balloons, as indicated in the Application. Further, the error in reference to the Schjeldahl et al. patent consisted of having "13" replaced by "7." This is the same error that was present in reference to the 4,963,313 patent. Applicants request that these corrections to the specification be entered.

Application No. 10/634370
Page 8

Amendment After Final
Attorney Docket No. S63.2N-7132-US03

Claim Rejections - 35 USC § 112

The Office Action rejects claim 33 under 35 USC § 112, first paragraph. This rejection is traversed.

As asserted above in the section discussing the specification, Forman (US 5826588), incorporated by reference into the immediate Application (see page 3, last paragraph), discloses a mandrel 40 oriented within a balloon that is rotatable about a longitudinal axis, and that the balloon rotates with the mandrel 40. See column 7, lines 1; 5-6; and 21. Therefore, the Application clearly supports "placing the balloon on a mandrel having a longitudinal axis and rotating the mandrel around the mandrel longitudinal axis to rotate the balloon thereon," as recited in claim 33.

The Office Action notes that Figures 3 and 4 of the immediate application show grinding of a balloon preform (parison), as opposed to a balloon. Applicants assert that the Application does disclose removing material "from a balloon that has already been formed," and "grinding subsequent to stretching." See page 11, lines 18-23.

Therefore, Applicants assert that a person of ordinary skill in the art viewing the application would have understood that the Applicants had possession of the invention of claim 33 at the time of filing. Accordingly, Applicants request withdrawal of the rejection under 35 USC § 112, first paragraph.

Claim Rejections - 35 USC § 103

The Office Action rejects, under 35 USC § 103, claims 33-37 and 39-41 over Wang in view of Wand. These rejections are traversed.

Applicants assert that Wang in view of Wand do not disclose or suggest all of the limitations of the rejected claims, and that there is no prior art motivation to modify either reference to arrive at the invention of the rejected claims.

Wang teaches a method for forming a balloon comprising the steps of extruding a segment of thermoplastic material, maintaining the center portion at a temperature below the glass transition of the thermoplastic material, drawing the segment to a predetermined length, wherein after the drawing the wall thickness of the center portion does not appreciably change, and expanding the segment in a mold to produce the balloon. See Abstract.

Application No. 10/634370
Page 9

Amendment After Final
Attorney Docket No. S63.2N-7132-US03

Wand teaches a method for forming a balloon including providing a tubular parison having a thick working section that tapers into thinner wall sections. The parison is molded under heat and pressure, wherein the parison transitions into a balloon with an essentially constant wall thickness. See column 2, lines 30-53.

Neither Wang nor Wand disclose or suggest "placing the balloon on a mandrel having a longitudinal axis and rotating the mandrel around the mandrel longitudinal axis to rotate the balloon thereon," as recited in claim 33.

Wang does disclose a mandrel, but disclosure of the mandrel is limited to a discussion in the Background of the Invention section of US 5087394, which teaches a method of stretching a parison prior to blow molding the parison into a balloon. See column 2, lines 53-65. Wang does not teach placing a balloon on a mandrel. Wang further does not teach rotating the mandrel to rotate the balloon thereon.

Similarly, Wand does disclose a mandrel, but disclosure of the mandrel is limited to a discussion of an extrusion method used to form the variable thickness parison. See column 2, line 54-column 3, line 13. The extruded parison is then molded under heat and pressure to form a balloon. See column 3, lines 14-19. Wand does not teach placing a balloon on a mandrel or rotating the mandrel to rotate the balloon thereon.

Neither Wang nor Wand disclose or suggest "positioning a material removal device in contact with an outer surface of at least a section of the rotating balloon to thereby remove balloon material from a portion of at least one of the proximal shaft section and the distal shaft section to form a shaft section having a first portion with a substantially uniform first diameter and a second portion with a substantially uniform second diameter, different than the first diameter," as recited in claim 33.

Wang discloses a method of stretching a tubular parison. See e.g. column 5, lines 1-16. After the stretching process, the tubing is expanded using internal pressure [i.e. molded] to form a balloon. See column 6, lines 50-51. Wang does not discuss removing material from a balloon.

Wand discloses a method of providing a shaped parison 30 and blow molding the shaped parison to form a balloon 12. See column 4, lines 7-23. Wand teaches a method of providing the shaped parison by forming a tubular member and thinning the wall of the tubular

Application No. 10/634370
Page 10

Amendment After Final
Attorney Docket No. S63.2N-7132-US03

member by "machining, abrading or other suitable means." See column 2, lines 45-53. Figure 5 shows the shaped parison, and it is clear that material has been removed from an inner surface of the parison. Wand does not disclose removing material from an outer surface of the parison. Wand does not disclose removing material from any portion of a balloon.

The Office Action recites at page 3, "A balloon can be inflated at a room temperature, but a balloon preform (parison) is not inflatable at the room temperature." Thus, the Examiner has taken the position that a parison is not a balloon. Applicants agree that a parison is by definition a precursor to a balloon, and therefore not a balloon. Removing material from the parison prevents the removed material from ever becoming part of a balloon. Therefore, Wand clearly does not disclose or suggest removing material from a balloon.

The Office Action further makes an inherency argument with respect to Wang. Wang discloses that it is desirable to have cone and waist walls with uniform thicknesses. See column 2, lines 30-33. The Office Action asserts that, inherently, due to manufacturing tolerances, the uniform thicknesses of the waist portions are actually different from one another. See Office Action page 5, last paragraph.

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51.

In this case, nothing in the record shows that a variation in the thicknesses is necessarily present in the Wand device. It is entirely possible that the waist portions will have a uniform thickness, as taught by the reference.

Applicants assert that there is no prior art motivation to modify either reference to arrive at the invention of claim 33. Both Wang and Wand disclose methods of shaping a parison prior to transforming the parison into a balloon via a molding process. Neither reference discloses or suggests removing material from a balloon that has already been formed. Because

Application No. 10/634370
Page 11

Amendment After Final
Attorney Docket No. S63.2N-7132-US03

any shaping operations taught by the applied references are performed on a parison prior to molding, modification of the teachings to first mold the balloon and then perform subsequent shaping operations would change the principle of operation of the prior art methods.

If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

There is absolutely no teaching in Wang or Wand that suggests a desirability to perform shaping operations on a balloon after it has been molded.

The Office Action asserts at page 4 that Wand discloses a material removal process. Figure 5 of Wand depicts the shaped parison prior to molding, and it is clear that material has been removed from an inner surface of the parison. When removing material from the inner surface, it is likely that a mandrel could not be positioned within the parison. Thus, the material removal process disclosed by Wand teaches away from the claimed method of placing a balloon on a mandrel and positioning a material removal device in contact with an outer surface of the balloon.

Further with respect to the parison/balloon distinction, a person of ordinary skill in the art would recognize that a parison is easier to machine than a balloon because the greater wall thickness of the parison imparts greater structural integrity. Further, the subsequent balloon forming step allows for mold-smoothing of any surface irregularities introduced during machining of the parison. For at least the reasons that balloons are thinner and that mold-smoothing does not occur after balloon formation, a person of ordinary skill in the art would not consider it obvious to remove material from the balloon rather than the parison as taught by Wand.

Thus, Applicants assert that claim 33 is patentable over Wang in view of Wand. Claims 34-41 depend from claim 33 and are therefore patentable for at least the reasons discussed with respect to claim 33. Accordingly, Applicants request withdrawal of the rejections under 35 USC § 103.

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Application No. 10/634370
Page 12

Amendment After Final
Attorney Docket No. S63.2N-7132-US03

Conclusion

Based on at least the foregoing remarks, Applicants respectfully submit this application is in condition for allowance. Withdrawal of the restriction of claim 38 is requested. Favorable consideration and prompt allowance of claims 33-41 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: November 8, 2005

By: _____

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